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Award Number: W81XWH-08-2-0047

TITLE: Innovative Service Delivery for Secondary Prevention of PTSD in At-Risk OIF-OEF Service Men and Women

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REPORT DATE: April 2011

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release; distribution unlimited

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<b>REPORT DOCUMENTATION PAGE</b>				<i>Form Approved</i> <b>OMB No. 0704-0188</b>	
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<b>1. REPORT DATE (DD-MM-YYYY)</b> 01-04-2011		<b>2. REPORT TYPE</b> Annual		<b>3. DATES COVERED (From - To)</b> 1 APR 2010-31 MAR 2011	
<b>4. TITLE AND SUBTITLE</b>  Innovative Service Delivery for Secondary Prevention of PTSD in At-Risk OIF-OEF Service Men and Women				<b>5a. CONTRACT NUMBER</b>	
				<b>5b. GRANT NUMBER</b> W81XWH-08-2-0047	
				<b>5c. PROGRAM ELEMENT NUMBER</b>	
<b>6. AUTHOR(S)</b>  Dr. Ronald Acierno  E-Mail: ron.acierno@musc.edu				<b>5d. PROJECT NUMBER</b>	
				<b>5e. TASK NUMBER</b>	
				<b>5f. WORK UNIT NUMBER</b>	
<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b>  Charleston Research Institute Charleston, SC 29401				<b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>	
<b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b> U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				<b>10. SPONSOR/MONITOR'S ACRONYM(S)</b>	
				<b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b>	
<b>12. DISTRIBUTION / AVAILABILITY STATEMENT</b> Approved for Public Release; Distribution Unlimited					
<b>13. SUPPLEMENTARY NOTES</b>					
<b>14. ABSTRACT</b> This report describes key research accomplishments for Innovative Service Delivery for Secondary Prevention of PTSD between 4/1/10 and 3/31/11. This report focuses on the primary objectives for our third year including: a) recruitment and enrollment, b) the development and implementation of an efficient, sustainable, study-referral infrastructure, and c) presentation of the project at two national conferences and submission and preparation of initial manuscripts. Additionally, we provide a detailed description of the study-related activities that occurred between 01/01/11 and 3/31/11.					
<b>15. SUBJECT TERMS</b> PTSD, OIF/OEF, Telemedicine, Behavioral Activation, Therapeutic Exposure, DOD/VHA research collaborations					
<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT</b>	<b>18. NUMBER OF PAGES</b>	<b>19a. NAME OF RESPONSIBLE PERSON</b>
<b>a. REPORT</b> U	<b>b. ABSTRACT</b> U	<b>c. THIS PAGE</b> U			<b>19b. TELEPHONE NUMBER (include area code)</b>
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## INTRODUCTION:

The current project has two primary objectives: 1) evaluate the effectiveness of an intervention to prevent the functional impairment associated with PTSD symptoms in post-deployed OIF/OEF service men and women, and 2) determine whether or not this program delivered via telepsychology will be as effective as in-person treatment. Behavioral Activation and Therapeutic Exposure (BATE) is an eight-session, manualized treatment program. Using a between-groups, repeated measures design, study participants will be randomized to one of two treatment conditions: BATE delivered via telepsychology (BATE-T), or BATE delivered in-person (BATE-IP). Participants will be assessed across primary and secondary outcome variables at five time points (pre-treatment, mid-treatment, post-treatment, and 3- and 12-month follow up).

## BODY:

The major tasks of the S.O.W. include (1) **recruit** 200 active duty or veteran participants with PTSD or Sub-Threshold PTSD and randomly **assign** to either in person or televideo based treatment for PTSD; (2) collect measures of PTSD and other psychopathology, attendance, patient satisfaction and cost at pre-treatment, post-treatment, and follow-up. Note that our S.O.W. has been amended and approved to address the more prevalent problem of chronic PTSD by including up to 33% of Vietnam Veterans, in addition to OIE/OEF and Persian Gulf Veterans.

### Report:

Between 04/01/2010 and 03/31/2011, 167 participants were screened and 47 were enrolled, bringing our total enrollment to date since the initiation of study procedures on 10/08/2008 to 98. Additionally, 20 participants completed post-test assessment (47 total), 11 completed three-month follow-up (35 total), and 18 completed 12-month follow-up (19 total).

### 3 Year Point Data Analysis

Participants were predominantly male (88.4%), African American (51.2%) followed by Caucasian (41.9%), Hispanic (2.3%), and other (4.7%), married (46.5%), employed (58.1%), not disabled (61.4%), and had a mean age of 32.7 years ( $SD = 9.02$ ). All participants endorsed symptoms consistent with either PTSD (62.8%) or subthreshold PTSD (37.2%) on the CAPs.

### *Clinical outcomes: Baseline to one-week post treatment*

To evaluate the overall efficacy of BA-TE, we ran paired t-tests for the PTSD Checklist-Military Version (PCL-M) and Beck Depression Inventory, Second Edition (BDI-II) for the entire sample. As presented in Table 1, these analyses revealed

significant within subject pre- to post-treatment reductions on the primary symptom measures (PCL-M,  $t = 5.2$ ,  $p < .001$ ; BDI-II,  $t = 2.8$ ,  $p = .008$ ).

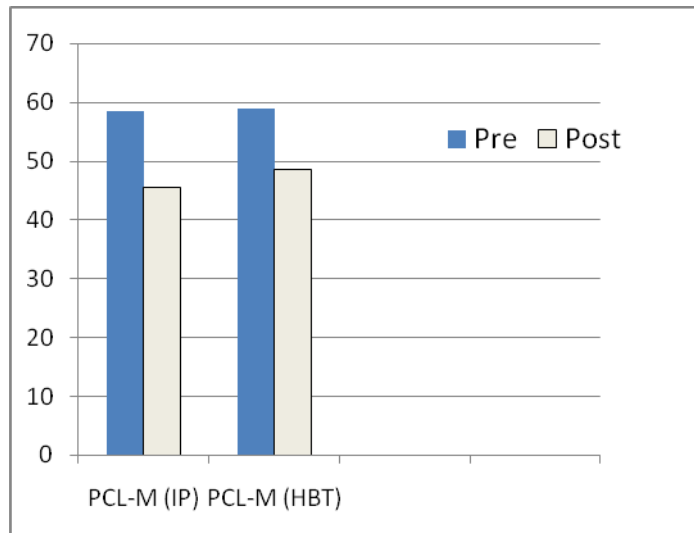
Table 1: Efficacy of BA-TE across all patients

Scale	Pre-Tx	Post-Tx	t	p
PCL-M ( $n = 45$ )	58.8 (13.15)	46.8 (17.9)	5.2	.000
BDI-II ( $n = 45$ )	23.8 (10.4)	18.8 (13.2)	2.8	.008

*Note.* Pre-Tx and Post-Tx columns are presented as means (standard deviations). Tx = treatment; PCL-M = PTSD Checklist – Military; BDI-II = Beck Depression Inventory – II

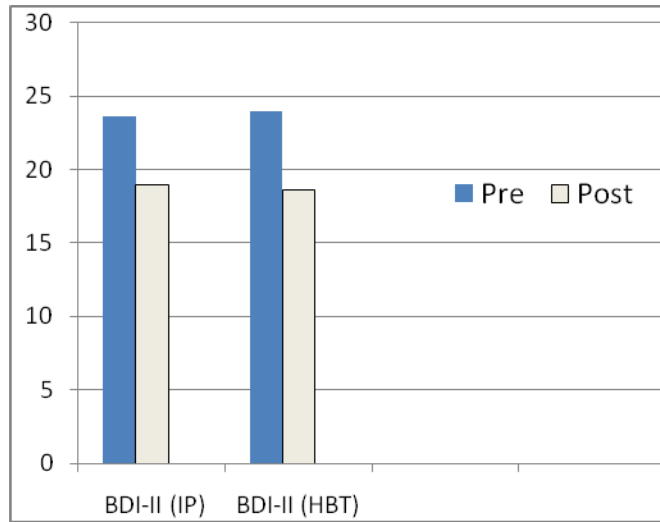
A series of 2x2 repeated measures ANOVAs were used to evaluate changes in PTSD and MDD symptom severity as a result of treatment, with time (Pre/Post PCL-M scores and BDI-II) serving as the within subjects factor, and condition (IP/HBT) serving as the between-subjects factor. As expected, one way ANOVAs failed to find differences across condition on any measures of baseline PTSD (CAPS,  $F = .036$ ,  $p = .851$ ; PCL-M,  $F = .066$ ,  $p = .799$ ); MDD (BDI-II,  $F = .116$ ,  $p = .735$ ); or Substance use/abuse (DAST,  $F = 3.61$ ,  $p = .065$ ; AUDIT,  $F = .126$ ,  $p = .724$ ). As illustrated in Figures 1 and 2, consistent with hypotheses, analyses revealed significant reductions in PTSD (PCL-M,  $F = 25.04$ ,  $p < .001$ ) and MDD symptoms over time (BDI-II,  $F = 7.46$ ,  $p = .009$ ) but no significant time by condition interactions (PCL-M,  $F = .312$ ,  $p = .579$ ; BDI-II,  $F = .036$ ,  $p = .850$ ).

Figure 1. PTSD symptoms by time and condition



*Note.* PCL-M: PTSD Checklist – Military; BDI-II: Beck Depression Inventory – II; IP: In-person; HBT: Home-based telehealth

Figure 2. MDD symptoms by time and condition



Note. PCL-M: PTSD Checklist – Military; BDI-II: Beck Depression Inventory – II; IP: In-person; HBT: Home-based telehealth

### *Trends at three-month follow-up*

To date, 35 participants have completed the three-month follow-up assessment. Although tests of significance across condition are premature at this stage of the study, initial data suggest that participants maintain therapeutic gains three months post-treatment completion.

Table 2: Mean BDI-II and PCL-M Scores at Baseline, Post-Treatment, and 3-Month Follow-up

	Assessment Time Frame		
	Base (n=43)	Post (n=40)	3 month (n=34)
Overall BDI-II Mean	23.85 (SD= 10.98)	18.4 (SD=12.81)	17.84 (SD=12.93)
Overall PCL-M Mean	58.4 (SD=14.6)	46.10 (SD=17.8)	47.4 (SD=17.8)

Note. Base: One week prior to session 1; Post: One week post session 8; 3 month: 3 months post session 8; PCL-M: PTSD Checklist, Military; BDI-II: Beck Depression Inventory, Second edition; SD= standard deviation; n=number of participants.

### *Process Outcomes*

We ran a series of independent t tests to determine whether treatment satisfaction (CPOSS-VA), credibility, and service delivery perceptions differed across groups. As

illustrated in Tables 3, 4 and 5, participants in both conditions were highly satisfied with the treatment and mode of delivery and generally found the treatment to be credible. However, contrary to hypotheses, participants reported comparable treatment satisfaction, credibility, and service delivery perceptions scores across condition. Further, as illustrated in Tables 5 and 6, participants displayed comparable attrition rates.

Table 3: Overall Satisfaction with Services by Condition

Item	In Person	Tele	t	p
Tx Helpfulness	4.4	4.5	-0.18	0.868
Tx Quality	4.4	4.5	-0.60	0.550
Rec to a friend?	4.3	4.1	-0.76	0.449

*\*Items from the CPOSS VA (4=Very Good; 5=Excellent); IP=In-person, HBT=Home-based telehealth*

Table 4: Treatment Credibility by Condition

Item	In Person	Tele	t	p
Tx Logical	7.4	7.1	0.31	0.758
Tx Reduce Symptoms	5.8	5.7	0.20	0.841
Rec to a friend?	7.6	6.6	0.78	0.226
Reduce Other Fear	7.0	6.1	0.74	0.187

*\* Items from the Treatment Credibility Scales (1=Not at all; 5=Moderately Confident; 10=Very Confident)*

Table 5: Service Delivery Perceptions by Condition

Item	In Person	Tele	t	p
Comfort	4.1	4.6	-0.47	0.639
Quality of communication		4.6	4.5	0.77 0.446
How far drive if IP?	3.2	2.6	1.64	0.109
How far drive if tele?	2.2	2.0	0.36	0.724
Use service again	4.3	4.1	0.75	0.459
Overall satisfaction	4.3	4.7	-1.67	0.102

*\* Items from the Service Delivery Perceptions Questionnaire (For items 1, 2, & 5: 1=Very Uncomfortable/Poor/Very Unlikely; 5=Very Comfortable/ Excellent/Very likely; for items 3 & 4: 1=0-10 miles; 2=11-20 miles; 3= 21-40 miles; 4=41-60 miles; 5=over 60 miles)*

## **KEY RESEARCH ACCOMPLISHMENTS:**

- Ninety-eight participants have been enrolled to date; 47 participants have completed treatment.
- Team representatives established relationships with clinicians at our two primary care clinic annexes located in the Trident Hospital and the Charleston Naval Weapons Station. Since these collaborations began, we have received over 50 referrals to the study and have enrolled 13 participants.
- An amendment to the statement of work to allow the enrollment of Vietnam and Persian Gulf veterans into the study was approved.
- Three manuscripts were accepted for publication (see next section).
- We presented preliminary findings at several national conferences (see next section).

## **REPORTABLE OUTCOMES:**

- Three manuscripts were accepted for publication and are currently in press:

Strachan, M., Gros, D., Ruggiero, K., Lejuez, C. & Acierno, R. (In press). An integrated approach to delivering exposure-based treatment for symptoms of PTSD and depression in OIF/OEF Veterans: Preliminary findings. *Behavior Therapy*.

Gros, D., Strachan, M., Knapp, R., Frueh, B., Egede, L., Lejuez, C., Tuerk, P., & Acierno, R. (In press). Innovative service delivery for the secondary prevention of at-risk OIF/OEF service men and women. *Contemporary Clinical Trials*.

Gros, D.F., Veronee, K., Strachan, M., Ruggiero, K.J., & Acierno, R. (In Press). Managing suicidality in home-based telehealth. *Journal of Telemedicine and Telecare*.

- The research team presented at many national conferences:

Strachan, M., Parker, J., Warner, C., Welsh, K., Muzzy, W., Boswell, J., Lejuez, C., & Acierno, R. (March 2011). Building a Collaborative Infrastructure for Research: Lessons Learned. Paper presented at the 13<sup>th</sup> Annual Armed Forces Public Health Conference, Hampton Roads, VA.

Strachan, M., Brown, C., Veronee, K., Welsh, K., Price, M., Gros, D.F., & Acierno, R. (March 2011). Legal issues relevant to the diagnosis and treatment of PTSD in OIF/OEF populations. Poster presented at the International Congress of Psychology and Law, Miami, FL.



- Acierno, R. (February 2010). Secondary prevention of PTSD in at risk OIF-OEF service men and women: BA-TE via HOME based telemedicine. Paper presented at the MOMRP/CDMRP PTSD IPR Meeting.
- Price, M., Gros, D. F., Strachan, M., Tuerk, P. W., Yoder, M., Ruggiero, K. J., Egede, L. E., Lejuez, C.W., Acierno, R. (February 2011). Comparison of general health outcomes for African Americans and Caucasians after outpatient treatment for PTSD. Poster presented at the VA HSR&D 2011 National Meeting, Baltimore, MD.
- Acierno, R. (November 2010). Two home based telemedicine treatments of PTSD. Symposium paper presented at the ABCT 44<sup>th</sup> Annual Convention in San Francisco, CA.
- Strachan, M., Gros, D.F., Ruggiero, K.J., Lejuez, C.W., Tuerk, P.W., & Acierno, R. (November 2010). Predictors of patient satisfaction in OEF/OIF Veterans with posttraumatic stress disorder. Poster presented at the Annual Meeting of the Association for Behavioral and Cognitive Therapies, San Francisco, CA.
- Price, M., Strachan, M., Gros, D.F., Ruggiero, K.J., Acierno, R. (November 2010). Examination of PTSD and depression treatment response for Behavioral Activation and Therapeutic Exposure. Poster presented at the Annual Meeting of the Association for Behavioral and Cognitive Therapies, San Francisco, CA.
- Veronee, K., Gros, D.F., Strachan, M., Price, M., Ruggiero, K.J., & Acierno, R. (November 2010). Managing suicidality in home-based telehealth exposure therapy for combat-related PTSD: A case presentation of an OEF Veteran. Poster presented at the Annual Meeting of the Association for Behavioral and Cognitive Therapies, San Francisco, CA.
- Gros, D.F., Strachan, M., Ruggiero, K.J., Tuerk, P.W., Lejuez, C.W., & Acierno, R. (November 2010). Predictors of treatment completion in OEF/OIF Veterans with posttraumatic stress disorder. Poster presented at the Annual Meeting of the Association for Behavioral and Cognitive Therapies, San Francisco, CA.

## **CONCLUSION:**

Recruitment has increased dramatically with the activation of a second recruitment site. Moreover, the recent inclusion of Vietnam Veterans two weeks ago will additionally enhance recruitment success. This inclusion was predicated on the fact that virtually all active duty and Veteran service men and women who seek services for PTSD do so more than 6 months post-symptom presentation. As such, the prototypic PTSD case treated in Active Duty and Veteran populations is Chronic PTSD. This inclusion modification will allow us to speak to the effectiveness of telemedicine delivered BA-TE with both distal and recent chronic populations.

Preliminary results are consistent with current literature that suggests behavior therapies can be safely and effectively implemented via home-based telehealth technology and that telehealth service delivery yields reductions in symptomatology that are comparable to in-person service delivery. Further, participants who receive behavior therapy via telehealth report comparable treatment satisfaction, credibility, and service

delivery perceptions to patients who receive exposure therapy via conventional in-person service delivery.

Thus far, study findings are encouraging. On measures of both PTSD and MDD, within group improvements are evident, but no differences between telemedicine and in person conditions are evident. The latter findings are tempered, however, because power is still low relative to that suggested as necessary in non-inferiority designs. Nonetheless, lack of significant differences between modalities, with significant improvement within both modalities is worthy of note.

**REFERENCES:**

None

**APPENDICES:**

The 3 research articles and 9 presentations are available upon request.